

REMARKS

Claims 54 and 55 are pending in this application. Claim 54 and 55 are rejected under 35 USC 103(a) over Wang et al. (WO/98/56312) in view of Jamiolkowski et al. (US 4,889,119). Applicants respectfully traverse.

Applicants are claiming a stent comprising an inner core made from a blend of a first biodegradable polymer component and a second biodegradable polymer component. The first biodegradable polymer component comprises a lactide/glycolide copolymer having at least about 80 mole percent of polymerized glycolide, and the second biodegradable polymer component comprises a lactide-rich copolymer comprising at least about 50 mole percent of polymerized lactide. The blend includes at least about 50 weight percent of the first polymer component and at least about 5 weight percent of the second polymer component. The claimed stent also includes an outer section covering the inner core and which is formed from monomers selected from the group consisting of lactide, glycolide, para-dioxanone, trimethylene carbonate, caprolactone, and combinations thereof. The biodegradation rate of the outer section is greater than the biodegradation rate of the inner core.

As acknowledged in the Office Action, Wang fails to teach a stent having an inner core comprising a blend of two biodegradable polymer components. Homopolymers and copolymers that may be used are noted at page 4, line 27 to page 5, line 7. Preferred polymers are PGA and PLLA/PGA copolymers. Applicants respectfully submit, however, that there is no suggestion of preparing blends of glycolide-rich copolymers with lactide-rich copolymers. Polymers suggested for use as the outer covering material in Wang include polyesters, polyamides, polyanhydrides and polyorthoesters, with polyanhydrides and polyorthoesters being more preferred (page 5, lines 8-10). Also as acknowledged in the Office Action, Wang permits a structure where the inner layer may biodegrade faster than the outer layer, "or", the outer layer may degrade faster than the inner layer.

Jamiolkowski teaches surgical fasteners that comprise a blend of at least two polymers, one of which has a high lactide content, and one of which has a high glycolide content. The polymer blend contains from about 65-85 weight percent of polymerized glycolide, with the high glycolide polymer comprising at least 50 weight percent of the blend (Col. 3, ll 45-52). The high glycolide polymer is either a polyglycolide homopolymer or a

glycolide/lactide copolymer containing at least about 90 percent glycolide (Col 5, ll 20-23). The high lactide polymer is either a polylactide homopolymer, or a lactide copolymer comprising at least 50, and more preferably 75 percent lactide (Col 5, ll 25-29). Polymer blends exemplified in Jamiolkowski include blends of polyglycolide (PGA) and polylactide (PLA) homopolymers (Examples 1 and 2) and a blend of a PGA homopolymer and a lactide/glycolide (L/G) copolymer (Example 3). Other noted polymer blends include blends of PLA and PGA homopolymer and blends of PGA with various L/G copolymers (Col 14, ll 16-47).

The Office Action states that “it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the material of the outer layer of Wang et al.’s stent with the material as disclosed by Jamiolkowski et al.. Doing so would amount to mere substitution of one material for another within the same art that perform equally well in Wang et al.’s stent.” Applicants respectfully disagree.

Initially, Applicants are claiming a stent and Wang discloses a stent, while Jamiolkowski discloses surgical staples. As such, while all involve medical devices, stents and surgical staples are very different both in structure, function and required properties, and material selection for a stent and a surgical staple will be based on different criteria. Furthermore, performance of one device versus the other device is not relevant given their differences. As such, Applicants respectfully submit that the material selection suggested by the Examiner is not a “mere substitution” of material within the same art. The uses of the devices are very different.

Additionally, Applicants respectfully submit that in order to render claims 54 and 55 obvious, one first must choose a stent embodiment of Wang where the outer covering material degrades faster than the inner core material. As noted above, Wang shows no preference of one over the other and Jamiolkowski provides no further suggestion in that it is silent as to stents and particularly to stents having an inner core and an outer covering material having different biodegradation rates. One then must choose to modify the inner core material of Wang to comprise a blend of two copolymers as claimed, even though Wang expressly discloses using unblended polymers or copolymers. With respect to Jamiolkowski, Applicants respectfully submit that Jamiolkowski is silent as to stents and therefore can offer

no teaching or suggestion that would motivate one skilled in the art to modify the material of the inner core of Wang as stated by the Office Action.

Applicants respectfully submit that in order to modify Wang in view of Jamiolkowski, as suggested by the Office Action, there must be some reasonable suggestion within the references to make such modification with the reasonable expectation of success. Applicants respectfully submit that neither Wang nor Jamiolkowski, alone or in combination, provide such reasonable suggestion, and that making such a modification would require picking and choosing in hindsight selection, which Applicants respectfully submit is improper.

Applicants respectfully submit that claims 54 and 55 are patentable under 35 U.S.C. 103(a) over Wang in view of Jamiolkowski and request that the rejection of those claims be withdrawn. Applicants further respectfully request a Notice of Allowance with respect to the claims.

Respectfully submitted,

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